NAPM

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NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS
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August 2, 1999

Mary Fanning, MD
Associate Director of Medical Affairs
Office of Generic Drugs
U.S. Food and Drug Administration
7500 Standish Place HFD-600
Rockville, MD 20855-2773

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Copies to Dockets HFA 305
Number 99D-0236

RE: Guidance for Industry: Skin Irritation and Sensitization of Generic Transdermal Drug Products

Dear Dr. Fanning,

The National Association of Pharmaceutical Manufacturers (NAPM) is the national trade organization representing manufacturers, distributors and repackagers of generic multisource prescription drugs, OTC drugs, dietary supplements and veterinary drugs. The organization prides itself in serving the needs of its members and has been heavily involved in legislative, legal, regulatory and technical issues.

NAPM wishes to comment on the Guidance for Industry: *Skin Irritation and Sensitization of Generic Transdermal Drug Products* for which we have some major concerns.

NAPM considers the FDA requirement for testing skin irritation and sensitization for each ANDA submission of a generic transdermal drug product submission unwarranted. Both topical and transdermal generic drug products use excipients that (1) are no different then those used for approved drug products and (2) have been well characterized for safety including skin irritation and sensitization. There is absolutely no rationale for performing additional tests on these excipients other then the usual skin evaluation for irritation that is performed concurrently with a biostudy.

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NAPM suggests that the Agency publishes a list of excipients that may be used in topical and transdermal drug products without performing elaborate skin irritation and sensitization studies. These skin irritation and sensitization studies are quite expensive, over $1 million, and time consuming. The Agency has already published an "Inactive Ingredient Guide" for oral drug products. Similarly, an official list of inactive ingredients topical and transdermal drug products could be published by FDA. Such a list would save the industry the time and cost in performing skin irritation and sensitization studies and save the FDA time for review of an ANDA submission.

NAPM does agree with FDA's requirement for testing skin irritation and sensitization for each ANDA submission of a generic transdermal drug product submission that contains any excipient whose safety has not been studied nor reported in the scientific literature.

We thank you for the opportunity to submit our comments. We hope that our comments are clear and welcome any questions that you may have.

Sincerely,

Leon Shargel

Leon Shargel, Ph.D.
Vice President and Technical Director

cc: Doug Sporn, FDA/OGD
Roger Williams, MD, FDA/OPS

m.a. Agtins - DoS

From: wildskunk@capecod.net on 06/02/99 08:48 AM GMT

To: president@Whitehouse.GOV
cc:
Subject: Help Stop Overfishing

6905 '99 AUG 20 P1:38

Dear President Clinton:

I am writing to urge your support for a strong global plan of action for reducing fishing capacity to sustainable levels when world governments meet in Rome in October under the direction of the United Nations Food and Agriculture Organization.

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According to a new report by World Wildlife Fund, the world's fishing states will have to reduce the world fleet by two-thirds in order to bring fishing fleet capacity into line with sustainable fishing levels (levels that ensure renewal of fish stocks). Excess fishing power threatens fish stocks as well as the financial viability of the worldwide fishing industry.

At the upcoming FAO consultation, I urge you to ensure that the plan of action includes the following measures:

* Requirements that new international guidelines be drafted to ensure that subsidies to the fishing industry do not contribute to fishing overcapacity.

* Targets for each individual fishery in a country's fishing zone (so that excess fishing capacity is not shifted to fisheries with the most vulnerable stocks).

* Prohibition of export of excess capacity to another country or to a high seas fishery.

* Temporary bans on additions of new capacity to any international fishery if species targeted by that fishery are fully exploited.

* Securing participation of nonmembers of regional agreements in plans to manage capacity by redistributing a portion of existing catch quotas to them.

* Streamlined procedures for trade sanctions against

vessels that violate regional conservation measures.

You can help create a legacy of healthy fisheries and oceans by playing a strong leadership role in reducing the overcapacity of the world's fishing fleets.

Sincerely,

Donna Backus
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